

## REMARKS

In the Office Action mailed March 23, 2009 from the United States Patent and Trademark Office, claims 1-11 were rejected under 35 U.S.C. 112, first paragraph; claims 1-11 under 35 U.S.C. 103(a) as being unpatentable over Kelly (US 6,340,703) in view of Chang et al. (US 2006/00996900 A1) in view of Davis (US 5,708,038) in view of Elkins, R. (1998) in view of Flockhart et al. (WO 9307901 A1) in view of Wang et al. (2002).

### Rejections under 35 U.S.C. § 112

Claims 1-11 were rejected under 35 U.S.C. § 112, first paragraph. The pending Action has indicated that the claim term “liquid” in claims 1 and 7 was not supported by the specification as originally filed. Applicant has deleted the term “liquid” from claims 1 and 7, and respectfully requests that the 35 U.S.C. § 112, first paragraph rejection be withdrawn at this time.

### Double Patenting Rejections

Applicant recognizes the provisional double patenting rejections and may file Terminal Disclaimers once that is the only remaining rejection to the present application.

### Rejections under 35 U.S.C. § 103(a)

M.P.E.P. § 2141 sets forth the *Graham* factual enquiries that should be considered when making an obviousness rejection under Section 103: 1) ascertaining the scope and content of the prior art; 2) ascertaining the differences between the claimed invention and the prior art; and 3) resolving the level of ordinary skill in the pertinent art. (Citing *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966).) In addition, M.P.E.P. §§ 2141 and 2142 set forth that “the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit.” (Citing *KSR International Co. v. Teleflex Inc. (KSR)*, 550 U.S. \_\_\_, 82 USPQ2d 1385 (2007).)

The M.P.E.P. provides several examples of rationales that can support a rejection under 35 U.S.C. § 103. Each rationale is dependent on showing known elements from the prior art corresponding to the limitations of the claimed invention. Therefore, for a rejection under Section 103 to stand, it must explicitly set forth 1) factual findings

showing that each claim element was known in the art at the time of the invention, and 2) factual findings showing that one of ordinary skill in the art, at the time of the invention, would have found it obvious to modify or combine the teachings to arrive at the claimed invention. (See, for example, the enumerated required articulations set forth in M.P.E.P. § 2143 for each lettered rationale.)

Applicant respectfully submits that the cited references, either alone or in combination, do not teach or suggest all the limitations claimed in the claim set provided herein. Applicant also respectfully submits that the Office Action has failed to show how one of skill in the art would have found it obvious to overcome the differences between the prior art and the claimed invention to arrive at the claimed invention.

The claimed invention involves ranges, which produce unexpected results. The process for utilizing a leaf extract according to the claims of the present invention have produced unexpected estrogenic affects. The prior art which indicates only that administration of whole foodstuffs containing isoflavones have shown no consistent estrogenic effect. In contrast to the inconsistent results detailed in the cited references, administration of a leaf extract according to the claims of the present invention produced an estrogenic effect nearly  $\frac{1}{2}$  as potent as that shown by estradiol.

Additionally, the inventive processing methods utilized, and administration of the claimed invention, have produced unexpected estrogenic effects when taken in view of the prior art. The unexpected result that increased concentrations of *Morinda citrifolia* leaf extracts result in an inhibition of enzyme induction is not taught in the cited references. In a non-limiting example, the *Morinda citrifolia* leaf extract exerted a significant induction of alkaline phosphatase, and maximum effect was achieved at 0.3 ml/ml (representing 30 mg dry leaves/ml), Specification, page 23. Higher concentrations caused an inhibition of enzyme induction.

Kelly fails to disclose the claimed ranges of quercetin and rutin, and fails to teach or fairly suggest the unexpected result that higher concentrations of leaf extract result in inhibition of enzyme induction. Kelly indicates that producing a consistent estrogenic effect by administration of isolated biologically active compounds was beyond the reach of one skilled in the art, and that the interplay between various compounds was

sufficiently complicated so as to obfuscate which combinations of compounds would effectively act to produce the desired estrogenic effect. Kelly, Column 3, lines 21-38.

Kelly indicated that the studies based only on the observation that Japanese women who typically have much high dietary levels of isoflavones compared to women in the Western countries, have a reportedly lower incident of acute menopausal syndrome effects contained obvious flaws, and could not stand scrutiny. Kelly, column 2, lines 68-column 3, line 20. Further, Kelley indicated that other studies done to date in this area were highly equivocal and that no consistent effect has been reported. Kelly indicated that it is not known which, if any, of the 700 or more identified isoflavones present in the leguminosae family may be responsible for any estrogenic effect, or whether a yet unidentified isoflavone comprise an estrogenic effect. Kelly, column 3, lines 21-38.

Accordingly, Kelly's disclosure makes clear that one of ordinary skill in the art would not have a reasonable expectation that any isoflavone would have successfully produced a significant estrogenic effect, and that there was not a finite number of identified predictable solutions known at the time to choose from. Rather, Kelly suggests that there was no reasonable expectation of success, and did not propose a finite number of isoflavones, or other identified predictable solutions, which may have been used as targets for subsequent clinical studies.

Chang disclosed a method for preparing a rutin-enriched composition from plant biomass, but fails to disclose the claimed ranges of rutin and quercetin, and fails to teach the unexpected result that higher concentrations cause an inhibition of enzyme induction. Chang discloses only that rutin is a flavanoid glycoside comprised of quercetin and rutinose, and that many beneficial health effects of rutin have been demonstrated. Chang's disclosure certainly does not provide insight that would have allowed one skilled in the art to solve the problem posed by Kelly, that administration of biologically active components had failed to produced consistent desirable estrogenic effects.

Kelly's concern with equivocal results is compounded by Davis' assertion, that even when effective, plant sterols produce only a mild estrogenic effect. Rather, Davis disclosed that the estrogenic activity of plant sterols has been estimated to be approximately 1/400 of that recorded for estrodile. Not only does Davis fail to disclose the claimed ranges of quercetin and rutin, and the unexpected result that higher

concentrations cause inhibition of enzyme induction, but Davis additionally teaches away from the use of plant sterols in favor of estrodile, as the plants discussed by Davis produce only a mild estrogenic effect, approximately 1/400 of that recorded for estrodile.

Elkins teaches only that *Morinda citrifolia* leaves contain beta-stiosterol. Elkins does little to solve the problem disclosed in Kelly and Davis of equivocal results which provide minimal estrogenic effect.


The magnitude of the unexpected result, as indicated in the table on page 23 of the present invention, is therefore significant and non-obvious in light of the art cited. Accordingly, Applicant respectfully submits the claims provided herein, are not anticipated or rendered obvious by the cited references. Verdegall Bros. v. Union Oil Co. of California, 814 F. 2d 628, 631 (Fed. Cir. 1987).

### CONCLUSION

Applicant submits that the amendments made herein do not add new matter and that the claims are now in condition for allowance. Accordingly, Applicant requests favorable reconsideration. If the Examiner has any questions or concerns regarding this communication, the Examiner is invited to call the undersigned.

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Respectfully submitted,

  
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